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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,835	07/05/2000	HANS PROPPERT	HARMS002	8966
530	7590	04/13/2004	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.	Applicant(s)	
09/554,835	PROPPERT, HANS	
Examiner	Art Unit	
Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 29 March 2004.  
2a) This action is **FINAL**.                            2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 3,8,14, 17, 19 and 21 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 3,8,14, 17, 19 and 21 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
    1. Certified copies of the priority documents have been received.  
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

The amendment filed 3/29/04 is acknowledged. Claims 3, 8, 14, 17, 19 and 21 are being examined on the merits

***Claim Rejections - 35 USC § 112***

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 8, 14, 17, 19 and 21 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague and indefinite in that the time period encompassed by “at least about 10 days” is unclear, even when reading the claim in light of the specification.

Claims 3 and 17 are vague and indefinite in that the “therapeutically effective amount” required to “prevent” diarrhea or to “prevent” intestinal colonization in all subjects for all conditions is not set forth with sufficient particularity in the as filed written disclosure. The time period of “preventing” is also unclear. Is it during administration?

***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that claim 8 is not vague and indefinite because in the time period disclosed in the specification pertains to 10-13 days after birth. However, the claim designated limitation is “at least about 10 days”, which is not equivalent to 10-13 days after birth.

Applicant argument raises issues of new matter regarding the stated claim limitation.

Applicant's arguments regarding claims 3 and 17 are noted. However, the arguments regarding “clear endpoints” are puzzling, particularly since the length of prevention is nowhere indicated. In addition, that diarrhea was “almost completely prevented” in some individuals is not dispositive of the issue raised regarding the “therapeutically effective amount” required to “prevent” diarrhea or to “prevent” intestinal colonization in all ruminant subjects.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country; before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Claim Rejections - 35 USC § 103***

Claims 3,8,14, 17, 19 and 21 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Hockertz [AT] taken with Lordinova-Zadnikova et al. [AR] and DE 196 37 936 [AL] for the reasons as stated in the last Office action and the further reasons below.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that none of the cited documents teach the use of strain *E. coli* DSM 6601 to treat pathogenic fungi in ruminants, nor do they suggest such a treatment. With all due respect, the claims are not limited to “treating”, but to rather to “treating or preventing” diarrhea mediated by pathogenic fungi or to “treating or preventing intestinal colonization of pathogenic fungi in a ruminant” There is no clear correlation between applicants’ arguments and the claims as written. “Prevention” cannot be equated with “treatment”.

Applicants also argue that the references do not suggest diarrhea in ruminants. However, at least Lordinova-Zadnikova et al. is clearly concerned with the intestinal colonization by the strain of interest in newborns, which would at least result in having the effect of preventing diarrhea in such newborns. Therefore, the reference strongly suggests that ingestion of the strain of interest has the desired effects regarding colonization and concomitant prevention of the establishment of

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pathogenic fungi in the intestine. It is not apparent that the intestinal mucosa of ruminants differs substantially from that of humans. Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success of successfully colonizing the intestinal mucosa of any mammal, including ruminants, by orally administering the strain of interest for that purpose.

As noted in the last Office action, the written disclosure is incomplete in the blank at page 9, line 11. No new matter may be added. Applicant did not address this point. As noted previously, there is no clear indication of the dosage administered to obtain the touted results.

Applicants indicate that a certified translation of the priority documents has been provided. However, this document is not of record.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.

*Irene Marx*  
Irene Marx  
Primary Examiner  
Art Unit 1651